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(71)
THE PROCTER & GAMBLE COMPANY,
One Procter & Gamble
Plaza , CINCINNATI, XX (US).

(72)
OUELLETTE, WILLIAM ROBERT (US).
DAVIS, LEANE KRISTINE (US).
KIMBLE, DAWN MICHELE (US).
CRAMER, RONALD DEAN (US).

(74)
Kirby Eades Gale Baker

(54) BANDAGES THERMIQUES ET JETABLES, POUR LE COU
(54) DISPOSABLE THERMAL NECK WRAP

(57)
The present invention relates to disposable thermal neck wraps (10) having one or more thermal packs (50) comprising a unified structure having at least one continuous layer of semirigid material, which has different stiffness characteristics over a range of temperatures, and a plurality of heat cells (26), wherein the heat energy is applied to specific areas of the upper back, neck and shoulders. More particularly, the present invention relates to disposable thermal neck wraps (10) having good conformity to user's upper back, neck, and shoulders which provides consistent, convenient, and comfortable heat application.

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(72) DAVIS, LEANE KRISTINE, US
(72) CRAMER, RONALD DEAN, US
(72) OUELLETTE, WILLIAM ROBERT, US
(72) KIMBLE, DAWN MICHELE, US
(71) THE PROCTER & GAMBLE COMPANY, US

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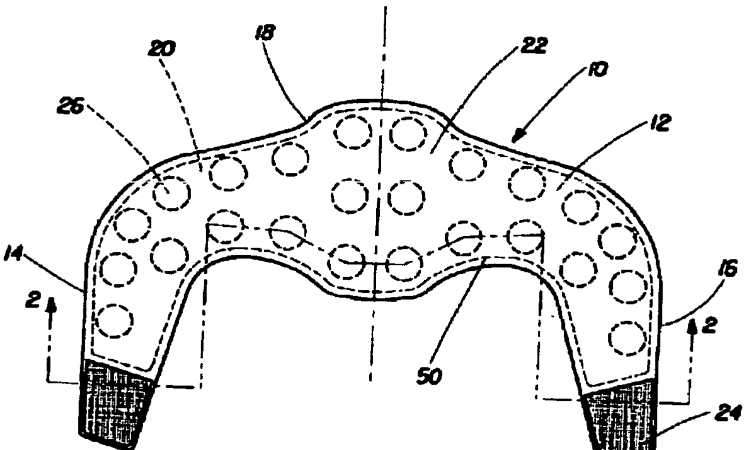
(54) **BANDAGES THERMIQUES ET JETABLES, POUR LE COU**
(54) **DISPOSABLE THERMAL NECK WRAP**



(57) Cette invention concerne des bandages thermiques (10), jetables, pour le cou, constitués d'au moins un ensemble thermique (50) comprenant une structure unifiée formée d'au moins une couche continue de matière semi-rigide dont les caractéristiques de rigidité varient en fonction de la température, et d'une pluralité de cellules thermiques (26); l'énergie thermique étant appliquée sur des zones spécifiques de la partie supérieure du dos, du cou et des épaules. D'une manière plus spécifique ces bandages (10) thermiques, jetables, pour le cou, se caractérisent par leur aptitude à bien se conformer au cou, aux épaules et à la partie supérieure du dos de l'utilisateur, ceci assurant en retour une application de chaleur efficace, commode et confortable.

(57) The present invention relates to disposable thermal neck wraps (10) having one or more thermal packs (50) comprising a unified structure having at least one continuous layer of semirigid material, which has different stiffness characteristics over a range of temperatures, and a plurality of heat cells (26), wherein the heat energy is applied to specific areas of the upper back, neck and shoulders. More particularly, the present invention relates to disposable thermal neck wraps (10) having good conformity to user's upper back, neck, and shoulders which provides consistent, convenient, and comfortable heat application.

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(71) Applicant: THE PROCTER & GAMBLE COMPANY [US/US]; One Procter & Gamble Plaza, Cincinnati, OH 45202 (US).

(72) Inventors: DAVIS, Leane, Kristine; 705-1/2 Maple Ridge Drive, Milford, OH 45150 (US). CRAMER, Ronald, Dean; 86 Oliver Road, Cincinnati, OH 45216 (US). OUELLETTE, William, Robert; 11987 Blackhawk Circle, Cincinnati, OH 45240 (US). KIMBLE, Dawn, Michele; 10140 Crossing Drive, Sharonville, OH 45241 (US).

(74) Agents: REED, T., David et al.; The Procter & Gamble Company, 5299 Spring Grove Avenue, Cincinnati, OH 45217 (US).

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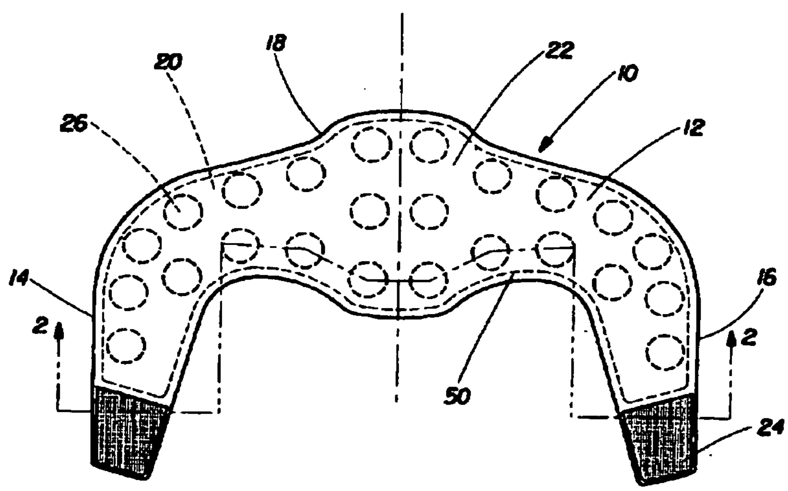

(57) Abstract

The present invention relates to disposable thermal neck wraps (10) having one or more thermal packs (50) comprising a unified structure having at least one continuous layer of semirigid material, which has different stiffness characteristics over a range of temperatures, and a plurality of heat cells (26), wherein the heat energy is applied to specific areas of the upper back, neck and shoulders. More particularly, the present invention relates to disposable thermal neck wraps (10) having good conformity to user's upper back, neck, and shoulders which provides consistent, convenient, and comfortable heat application.

DISPOSABLE THERMAL NECK WRAP

TECHNICAL FIELD

The present invention relates to disposable thermal neck wraps having one or more thermal packs comprising a plurality of individual heat cells, wherein the heat energy is applied to specific areas of the user's upper back, neck, and/or shoulders. More particularly, the present invention relates to disposable thermal neck wraps having good conformity to user's upper back, neck, and shoulders which provide consistent, convenient, and comfortable heat application.

BACKGROUND OF THE INVENTION

A common method of treating acute, recurrent, and/or chronic pain is by the topical application of heat to the afflicted area. Such heat treatments are used as a means of therapy for conditions which include aches, stiffness in muscles and joints, nerve pain, rheumatism and the like. Typically, the method for relieving pain using heat treatments has been to topically apply a relatively high heat, i. e., greater than about 40°C, for a short period of time, i. e., from about twenty minutes to about one hour.

Upper back, neck, and shoulder pain is generally associated with stress, bursitis, and upper back and neck muscular problems. Heating pads, hot water bottles, hot packs, hot towels, whirlpools, and hydrocollators have been commonly used to relieve the pain caused by such problems. Many of these devices employ reusable thermal packs containing, e.g., water and/or microwaveable gels. In general, most of these devices are inconvenient to use. Further, many of these thermal units or devices do not provide long lasting heat and also do not maintain a consistent temperature over long periods of time. The beneficial therapeutic effects from this administration of heat diminish after the heat source is removed.

The present inventors, however, have discovered that maintaining a sustained skin temperature of from about 32°C to about 50°C, preferably from about 32°C to about 45°C, more preferably from about 32°C to about 42°C, most preferably from about 32°C to about 39°C, still most preferably from about 32°C to about 37°C, for a period of from about twenty seconds to about twenty-four hours, preferably from about twenty minutes to about twenty hours, more preferably from about four hours to about sixteen hours, most preferably from about eight hours to about twelve hours, wherein the maximum skin temperature and the length of time of maintaining the skin

temperature at the maximum skin temperature may be appropriately selected by a person needing such treatment, such that the desired therapeutic benefits are achieved without any adverse events, such as skin burns which may be incurred by using a high temperature for a long period of time, substantially relieves acute, recurrent, and/or chronic upper back, neck, and/or shoulder pain, including skeletal, muscular, and/or referred upper back, neck, and/or shoulder pain, of a person having such pain.

The present inventors have further discovered that preferably maintaining a sustained skin temperature of from about 32°C to about 43°C, preferably from about 32°C to about 42°C, more preferably from about 32°C to about 41°C, most preferably from about 32°C to about 39°C, still most preferably from about 32°C to about 37°C, for a time period of greater than about 1 hour, preferably greater than about 4 hours, more preferably greater than about 8 hours, even more preferably greater than about 16 hours, most preferably about 24 hours, substantially relieves acute, recurrent, and/or chronic upper back, neck, and/or shoulder pain, including skeletal, muscular, and/or referred upper back, neck, and/or shoulder pain, of a person having such pain and substantially prolongs relief even after the heat source is removed from upper back, neck, and/or shoulder.

Disposable heat packs based on iron oxidation, such as those described in U.S. Patent Nos. 4,366,804, 4,649,895, 5,046,479 and Re. 32,026, are known. However, such devices have proven not totally satisfactory because many of these devices are bulky, cannot maintain a consistent and controlled temperature, have difficulty staying in place during use, and/or have unsatisfactory physical dimensions which hinder their effectiveness. Specifically, such devices cannot be easily incorporated into wraps which can comfortably conform to various body contours, and hence, they deliver short duration, inconsistent, inconvenient and/or uncomfortable heat application to the body.

The present inventors have developed disposable thermal neck wraps comprising one or more thermal packs having a unified structure, wherein each thermal pack comprises at least one continuous layer, preferably of a semirigid material, which is semirigid in specific areas of the thermal pack, yet which softens in between such areas when heated during use, most preferably comprising a coextruded material of polypropylene and ethylene vinyl acetate (EVA). The thermal pack or packs also comprises a plurality of individual heat cells, which typically comprise an exothermic composition, preferably comprising a specific iron oxidation chemistry, and having specific physical dimensions and fill characteristics, spaced apart and fixed within or to the unified structure of the thermal pack. Active heat cells, that is, heat cells having a temperature of about 35°C or greater, soften narrow portions of the continuous layer or layers of semirigid material immediately surrounding the heat cells. Any remaining

portions of the continuous layer or layers which surround the softened portions preferably remain more rigid. The narrow, softened portions act as hinges between the heat cells and between any remaining, cooler, more rigid portions, bending preferentially more than either the heat cells or more rigid portions. This results in thermal packs which possess sufficient rigidity to maintain structural support of the heat cells, to prevent unacceptable stretching of structures of the continuous layer or layers during processing or use, and to deter easy access to heat cell contents, while still maintaining good overall drape characteristics when heated. The thermal packs, when incorporated into the neck wraps of the present invention, provide efficient and effective heat coverage by having excellent conformity with the user's upper back, neck, and shoulders. These wraps also comprise alignment and position maintenance features.

The present inventors have also discovered that it may be desirable to selectively place heat cells, in the thermal pack or packs when incorporated into the neck wraps of the present invention, into positions fixed within or to the unified structure of the thermal pack, relative to each other which are sufficiently close so as to block some or all possible axes, which otherwise would have passed uninterrupted between the heat cells, through the thermal pack, or select regions thereof, to minimize or eliminate undesirable, uninterrupted fold lines, and/or to increase the structural support that the heat cell matrix imparts to the thermal pack. That is, placement of the heat cells into positions relative to each other which are sufficiently close to block some or all possible axes which would otherwise have passed uninterrupted, between the heat cells, causes the thermal packs to fold along a multiplicity of short interconnected fold lines oriented in a number of different directions relative to each other. Folding along a multiplicity of interconnected fold lines results in good overall drape characteristics.

It is therefore an object of the present invention to provide disposable thermal neck wraps which comprise one or more thermal packs, comprising a unified structure having at least one continuous layer, preferably of a semirigid material which has different stiffness characteristics over a range of temperatures, and a plurality of individual heat cells, which provide a controlled and sustained temperature and which reach their operating temperature range relatively quickly. The heat cells are spaced apart and fixed within or to the unified structure of the thermal pack.

It is also an object of the present invention to provide thermal neck wraps which have good overall drapability while maintaining sufficient rigidity to maintain structural support of the heat cells, to prevent unacceptable stretching of the continuous layer or layers during processing or use, and/or to deter easy access to heat cell contents.

It is a further object of the present invention to provide disposable thermal neck wraps which can be worn under outer clothing with minimal visibility, which have

alignment and position maintenance features, and which have a thermal element pattern that directs thermal energy to where it has the most therapeutic benefit.

It is a still further object of the present invention to provide methods of treating acute, recurrent, and/or chronic upper back, neck, and/or shoulder pain, including skeletal, muscular, and/or referred upper back, neck, and/or shoulder pain, of a person suffering from such pain, by maintaining a sustained skin temperature of from about 32°C to about 50°C for a period of time of from about twenty seconds to about twenty-four hours, preferably by maintaining a skin temperature of from about 32°C to about 43°C for a time period of greater than about 1 hour to provide prolonged relief from such pain.

These objectives and additional objectives will become readily apparent from the detailed description which follows.

SUMMARY OF THE INVENTION

The disposable thermal neck wraps of the present invention comprise at least one substantially U-shaped piece of flexible material having a first arm portion, a second arm portion, a central body portion therebetween, a body-facing surface, and an opposing outer surface, such that when the neck wrap is placed on a user, the central body portion is centered at the user's upper back and lower neck. First and second arm portions lay over the user's shoulders toward the user's chest.

The disposable thermal neck wraps of the present invention further comprise one or more thermal packs. The thermal packs comprise a unified structure having at least one continuous layer of a material which is preferably semirigid at a temperature of about 25°C, having a tensile strength of about 0.7 g/mm^2 or greater, and at least two-dimensional drape, and which is substantially less rigid at a temperature of 35°C or greater, having a tensile strength substantially less than the tensile strength of the material at about 25°C.

The continuous layer or layers of the present invention preferably comprise a coextruded material, more preferably a coextruded material comprising polypropylene, most preferably a coextruded material wherein a first side comprises polypropylene and a second side comprises a tie-layer of a low melt temperature copolymer, preferably EVA, preferably having a combined basis weight thickness of less than about 50 μm.

The thermal pack(s) further comprises a plurality of individual heat cells, preferably comprising a mixture of powdered iron, powdered carbon, water, and salt, which when exposed to oxygen, provides a controlled and sustained temperature and which reach their operating temperature range quickly. The heat cells are spaced apart and fixed within or to the unified structure of the thermal pack. Preferably the heat cells

are placed into positions fixed within or to the unified structure of the thermal pack, relative to each other and sufficiently close so that some or all of the possible axes that would otherwise pass uninterrupted between the heat cells are blocked by the heat cells to cause the thermal packs to fold along a multiplicity of short interconnected fold lines.

Preferably, the disposable thermal neck wraps of the present invention further comprise one or more attachment and/or positioning means fixedly attached to one or both distal ends of first and second arm portions, which serves to maintain the positioning of the thermal neck wrap during use by the wearer.

The present invention still further comprises methods of treating acute, recurrent, and/or chronic upper back, neck, and/or shoulder pain, including skeletal, muscular, and/or referred upper back, neck, and/or shoulder pain, of a person having such pain, by applying the disposable thermal neck wraps of the present invention to the upper back, neck, and/or shoulder of a person having such pain, to maintain a sustained skin temperature of from about 32°C to about 50°C for a period of time of from about twenty seconds to about twenty-four hours, preferably to maintain a skin temperature of from about 32°C to about 43°C for a time period of greater than about 1 hour, to provide prolonged relief from such pain.

All percentages and ratios used herein are by weight of the total composition, and all measurements made at 25°C, unless otherwise specified.

BRIEF DESCRIPTION OF THE DRAWINGS

While the specification concludes with claims which particularly point out and distinctly claim the present invention, it is believed that the present invention will be better understood from the following description of preferred embodiments, taken in conjunction with the accompanying drawings, in which like reference numerals identify identical elements and wherein:

FIG. 1 is a top plan view of a preferred embodiment of the disposable thermal neck wrap of the present invention, showing a preferred pattern of thermal packs and/or heat cells; and

FIG. 2 is a sectioned elevation view of FIG. 1, showing the laminate structure of the thermal neck wrap.

DETAILED DESCRIPTION OF THE INVENTION

The disposable thermal neck wraps of the present invention comprise one or more thermal packs having at least one continuous layer of a material which exhibits specific thermophysical properties, and a plurality of individual heat cells which preferably comprise an exothermic composition, spaced apart and fixed within or to the

structure of the disposable thermal pack. The material of the at least one continuous layer is preferably semirigid when at room temperature, i.e., about 25°C, or below, but softens and becomes substantially less rigid when heated to about 35°C, or greater. Therefore, when heat cells, which are fixed within or to the unified structure of the thermal packs, are active, that is at a heat cell temperature of about 35°C or greater, the narrow portion of the continuous layer or layers of material immediately surrounding each heat cell preferably softens and acts as a hinge between the heat cells and between any remaining, more rigid portions of the continuous layer or layers, bending preferentially more than either the heat cells or any cooler, more rigid portions. This results in thermal packs which possess sufficient rigidity to maintain structural support of the heat cells and prevent unacceptable stretching of structures of the continuous layer or layers during processing or use, while still maintaining good overall drape characteristics when heated. The disposable thermal neck wraps of the present invention provide consistent, convenient, and comfortable heat application, and an excellent conformity with user's upper back and the back portion of the user's neck, while retaining sufficient rigidity to deter easy access to heat cell contents.

"Disposable", as used herein, means that, while the thermal neck wraps of the present invention may be stored in a resealable, substantially air-impermeable container and reapplied to the user's body as often as required for the relief of pain, they are intended to be thrown away, i.e., deposited in a suitable trash receptacle, after the heat source, i.e., the heat cell(s) or thermal pack(s), has been fully expended.

"Heat cells", as used herein, means a unified structure, comprising an exothermic composition, preferably a specific iron oxidation chemistry, enclosed within two layers, wherein at least one layer may be oxygen permeable, capable of providing long lasting heat generation with improved temperature control, and having specific physical dimensions and fill characteristics. These heat cells can be used as individual heating units, or in a thermal pack comprising a plurality of individual heat cells which can also be easily incorporated into disposable body wraps, pads, and the like. Thermal packs and body wraps incorporating thermal packs adapt to a wide variety of body contours, thus providing consistent, convenient, and comfortable heat application.

"Plurality of heat cells", as used herein, means more than one, preferably more than two, more preferably more than three, most preferably more than four, heat cells.

"Agglomerated pre-compaction composition", as used herein, means the mixture of dry powdered ingredients, comprising iron powder, carbonaceous powder, metal salt(s), water-holding agent(s), agglomeration aid(s), and dry binder(s) prior to direct compaction.

"Direct compaction", as used herein, means a dry powder mixture is blended, compressed, and formed into pellets, tablets, or slugs without the use of typical wet binders/solutions to adhere the particulate(s) together. Alternatively, the dry powder mixture is blended and roll compacted or slugged, followed by milling and screening, creating directly compacted granules. Direct compaction may also be known as dry compaction.

"Heating element(s)", as used herein, means the exothermic, direct compacted, dry agglomerated pre-compaction composition formed into compaction articles, such as granules, pellets, slugs, and/or tablets capable of generating heat, after an aqueous solution such as water or brine (salt solution) is added, by the exothermic oxidation reaction of iron. Agglomeration granules of said agglomerated pre-compaction composition are also included as heating elements herein.

The "fill volume", as used herein, means the volume of the particulate composition or the compacted, water-swelled, heating element in the filled heat cell. The "void volume", as used herein, means the volume of the cell left unfilled by the particulate composition or the compacted, water-swelled, heating element in a finished heat cell, not including the unfilled space within a tablet comprising a hole or reservoir, in a finished heat cell, measured without differential pressure in the heat cell and without additional stretching or deformation of the substrate material. The "cell volume", as used herein, means the fill volume plus the void volume of the heat cell.

"Continuous layer or layers", as used herein, means one or more layers of a material which may be uninterrupted or partially, but not completely, interrupted by another material, holes, perforations, and the like, across its length and/or width.

"Rigid", as used herein, means the property of a material wherein the material may be flexible, yet is substantially stiff and unyielding, and which does not form fold lines in response to gravitational pull or other modest forces.

"Semirigid material", as used herein, means a material which is rigid to some degree or in some parts, i. e., having at least two-dimensional drape at a temperature of about 25°C, and exhibits a toughness to maintain structural support of the heat cells in an unsupported format, and/or prevent unacceptable stretching of structures of the material during processing or use, while still maintaining good overall drape characteristics when heated, and/or retaining sufficient rigidity to deter easy access to heat cell contents.

"Two dimensional drape", as used herein, means drape which occurs across a continuous layer or layers, across a thermal pack, or across a select region of a layer or layers, or thermal pack, exclusively along one axis, i.e., one fold line forms, at the expense of other axes in response to gravitational pull or other modest forces.

"Three dimensional drape", as used herein, means drape which simultaneously occurs across a continuous layer or layers, across a thermal pack, or across a select region of a layer or layers, or thermal pack, along two or more axes, i. e., two or more fold lines form, in response to gravitational pull or other modest forces.

"Fold lines", as used herein, means the line along which a material forms a temporary or permanent crease, ridge, or crest in response to gravitational pull or other modest forces.

It is understood that the disposable thermal neck wraps of the present invention may comprise one or more thermal packs. However, for clarity a disposable thermal neck wrap comprising a single thermal pack will be described herein.

Referring now to the drawings, and more particularly to Figs. 1 and 2, there is shown a preferred embodiment of the present invention, which provides a disposable thermal neck wrap with means for position maintenance, generally indicated as 10. Thermal neck wrap 10 comprises at least one piece of flexible material 12, having a first arm portion 14, a second arm portion 16, and a central body portion 18 therebetween. Wrap 10 has a body-facing surface 20 and an opposing outer surface 22. When neck wrap 10 is worn, first and second arm portions 14 and 16 extend over the shoulders of the wearer toward the upper chest. Central body portion 18 is located on the user's upper back and the back portion of the user's neck.

Flexible material 12 of wrap 10 comprises body-facing material 62 and outer surface material 64. Body-facing material 62 and outer surface material 64 may be selected from any number of suitable materials including, but not limited to, wovens, knits, films, foams and nonwovens including spunbond, carded, meltblown, hydroentangled, through-air bonded, air laid, and wet laid. These materials may be made from natural fibers including, but not limited to, cotton, wool, linen, or manmade polymeric materials such as polypropylene, polyester, nylon, polyethylene, metallocene catalyst polyethylene, and the like.

A material that has been found to be particularly suitable for body-facing material 62 is a carded thermally bonded nonwoven of polypropylene with a basis weight of about 65 g/m^2 (54 grams per square yard (gsy)). This material is available as grade #9354990 from Veratec, Walpole, MA.

A material that has been found to be particularly suitable for outer surface material 64 is a carded thermally bonded nonwoven of polypropylene with a basis weight of about 32 g/m^2 (27 gsy). This material is available as grade #9327786 from Veratec, Walpole, MA.

During use, thermal neck wrap 10 is draped over the shoulders of the wearer. Preferably, an attachment and/or positioning means, preferably adhesive patches 24, are

located toward the upper chest of the wearer and serve to maintain the positioning of thermal neck wrap 10. Preferably, one or more adhesive patches 24 are fixedly attached to one or both of the distal ends of first and second arm portions 14 and 16.

Adhesive patches 24 are preferably fixedly attached to outer surface 22 of first and second arms 14 and 16 near their respective distal ends, beyond the location of heat cells 26 of the thermal pack(s) 50, which are designed to reside in front of the shoulders, and of the heat cells 26 of thermal pack(s) 50 of body portion 18, which are designed to reside behind the shoulders of the wearer.

Preferably, adhesive patches 24 may be pressure sensitive adhesive circles, squares, or other shapes.

Adhesive patches 24 are preferably protected prior to use by a removable release paper 25. Upon use, removable release paper 25 is removed exposing adhesive patches 24. Adhesive patches 24 may then be applied against the underside of the wearer's clothing, or adhesive patch 24 of first arm 14 may be applied to the body facing surface 20 of second arm 16, or adhesive patch 24 of second arm 16 may be applied to the body facing surface 20 of first arm 14.

Alternatively, adhesive patches 24 may be fixedly attached to body-facing-surface 20 and applied to the skin of the user.

Adhesive patches 24 may be any number of suitable adhesive materials which is capable of attaching to clothing and/or skin. A particularly suitable material that has been used successfully is positioning adhesive 34-5598 available from National Starch and Chemical Co., Bridgewater, NJ. Release paper 25 may be any suitable polymeric film or paper which has been designed or treated to release from the adhesive used for adhesive patches 24. BL 25 MGA SILOX C3R/0 available from Akrosil has been shown to be suitable for this purpose.

Alternatively, adhesive patches 24 may be preapplied to a substrate prior to assembly of wrap 10. The substrate is then attached to outer surface material 64 by a suitable means.

Other types of attachment and/or positioning means which may be useful in the present invention include, but are limited to, hook and loop fastening systems.

The materials from which the wrap are constructed must be selected such that once they are combined in the product the product must be adapted to both easily drape over and conform to the body curvature and to provide minimal translation of compressive force along and in the plane of the product. In the present invention the layers are combined with pressure sensitive hot melt glue layers 60. Glue layer 60 is applied via a spiral glue application system at a level of approximately 0.31 to 1.55 mg/cm^2 (0.002 to 0.010 grams per square inch). A particularly suitable adhesive for

glue layer 60 is pressure sensitive hot melt adhesive 70-4589 available from National Starch & Chemical Co., Bridgewater, NJ. Alternatively, combining or assembly means may include, but not limited to, thermal dot bonding, melt blown hot melt glue, bead applied hot melt glue, ultrasonic, and/or pressure bonding.

Thermal neck wrap 10 further comprises one or more thermal packs 50. Each thermal pack 50 comprises a plurality of individual heat cells 26, preferably embedded within the laminate structure of the thermal pack 50. Alternatively, each thermal pack 50 may comprise a single continuous base layer 70, wherein individual or groups of heat cells 26 are fixedly attached and spaced apart across the base layer 70.

Heat cells 26 are spaced apart from each other and each heat cell 26 functions independently of the rest of the heat cells 26. While the heat cells may comprise any suitable composition providing heat, such as exothermic compositions, microwaveable compositions, heat of crystallization compositions, and the like, the preferred heat cell contains a densely packed, particulate exothermic composition 74 which substantially fills the available cell volume within the cell reducing any excess void volume thereby minimizing the ability of the particulate matter to shift within the cell. Alternatively, the exothermic composition 74 may be compressed into a hard tablet before being placed in each cell. Because the heat generating material is densely packed or compressed into a tablet, the heat cells 26 are not readily flexible. Therefore, the spacing apart of the cells and the materials selected for base layer 70 and cover layer 72 between the heat cells 26 allows each thermal pack 50 to easily conform to the user's upper back, neck, and shoulders.

Heat cells 26 are positioned within thermal pack 50 such that they are located within central body portion 18 and, preferably, first and second arms 14 and 16. When wrap 10 is properly positioned on the user, the heat cells 26 located away from first and second arms 14 and 16 are designed to reside behind or on top of the user's shoulders to approximate the shape and location of muscles in the user's upper back, lower neck, and shoulders. Heat cells 26 located near first and second arms 14 and 16 are designed to reside in front of or on top of the user's shoulders to provide a means of counter-balancing the weight of the heat cells 26 located in central body portion 18.

Base layer 70 and cover layer 72 are preferably continuous layers which may be made of any number suitable materials. Preferably, base layer 70 and/or cover layer 72 comprise materials which are semirigid at a temperature of about 25°C and which soften, i.e., becomes substantially less rigid, at a temperature of about 35°C, or greater. That is, the materials preferably have a tensile strength, within the elastic deformation range of the material, of about 0.7 g/mm^2 or greater, more preferably about 0.85 g/mm^2 or greater, most preferably about 1 g/mm^2 or greater, at about 25°C and a tensile

strength substantially less at about 35°C or greater. "Substantially less", as used herein, means that the tensile strength of the material at about 35°C, or greater, is statistically significantly less than the tensile strength at about 25°C, at an appropriate statistical confidence (i. e., 95%) and power (i. e., ≥90%).

Therefore, when heat cells 26, which are fixed within or to the unified structure of thermal pack 50, are active, that is at a heat cell temperature of from about 35°C to about 60°C, preferably from about 35°C to about 50°C, more preferably from about 35°C to about 45°C, and most preferably from about 35°C to about 40°C, the narrow portion of the continuous layer or layers of material immediately surrounding each heat cell softens and acts as a hinge between the heat cells and any remaining, cooler, more rigid portions of the continuous layer or layers, bending preferentially more than either the heat cell or more rigid portions. This results in thermal pack 50 which possess sufficient rigidity to maintain structural support of the heat cells and to prevent unacceptable stretching of structures of the continuous layer or layers during processing or use, while still maintaining good overall drape characteristics when heated. When thermal pack 50 of the present invention is incorporated into neck wrap 10, neck wrap 10 easily adapts to a wide variety of body contours, provides consistent, convenient, and comfortable heat application, and an excellent conformity with body forms, while retaining sufficient rigidity to prevent wrap 10 from folding or bunching during use and deter easy access to heat cell contents.

Typically, the tensile strength is measured using a simple tensile test on an electronic tensile test apparatus, such as a universal constant rate elongation tensile testing machine with computer, Instron Engineering Corp., Canton, MA. Any standard tensile test may be used, for example, material samples are cut into strips having a width of about 2.54 cm (about 1 inch) and a length of from about 7.5 cm to about 10 cm (about 3 to about 4 inches). The ends of the strips are placed into the jaws of the apparatus with enough tension to eliminate any slack, but without loading the load cell. The temperature of the sample is then allowed to stabilize at the desired test temperature. The load cell of the apparatus is set for about 22.7 kg (50 pound) load, the elongation set for 5 mm, and the crosshead speed is set for about 50 cm/min. The apparatus is started and the tensile strength data is collected by the computer. The sample is then removed from the apparatus.

The tensile strength is calculated as the slope of the tensile load vs. the extension during elastic deformation of the materials using the equation:

$$m = (L/E)$$

Where m = the slope in g/mm^2 during elastic deformation;
L = the load at extension in g/mm; and
E = the extension in mm.

Base layer 70 and/or cover layer 72 also preferably comprise at least two-dimensional drape at about 25°C, i. e., a single fold or crease occurs in the material along a single axis, and preferably three-dimensional drape at about 35°C or greater, i. e., two or more folds or creases occur along multiple axes. Drape may be determined by placing and centering a square sample, for example about 30 cm by about 30 cm (about 12 inches by about 12 inches), of material on the end of a cylindrical shaft with a pointed end, allowing the material to drape due to gravitational forces, and the number of fold lines counted. Material that exhibit one-dimensional drape, i. e., have no folds or creases in any direction, are determined to be rigid, while materials that exhibit at least two-dimensional drape, i. e., have at least one fold or crease line forming along at least one axis, are determined to be semirigid.

Different materials may be capable of satisfying the specified requirement for base layer 70 and/or cover layer 72 provided that the thickness is adjusted accordingly. Such materials may include, but are not limited to, polyethylene, polypropylene, nylon, polyester, polyvinyl chloride, polyvinylidene chloride, polyurethane, polystyrene, saponified ethylene-vinyl acetate copolymer, ethylene-vinyl acetate copolymer, natural rubber, reclaimed rubber, synthetic rubber, and mixtures thereof. These materials may be used alone, preferably extruded, more preferably coextruded, most preferably coextruded with a low melt temperature polymer including, but not limited to, ethylene vinyl acetate copolymer, low density polyethylene, and mixtures thereof.

Base layer 70 and cover layer 72 preferably comprise polypropylene, more preferably a coextruded material comprising polypropylene, most preferably a coextruded material wherein a first side comprises polypropylene, preferably from about 10% to about 90%, more preferably from about 40% to about 60%, of the total thickness of the material, and a second side comprises a tie-layer of a low melt temperature copolymer, preferably EVA. Base layer 70 and cover layer 72 preferably havea basis weight thickness of less than about 50 µm, more preferably less than about 40 µm, most preferably less than about 30 µm.

Base layer 70 and/or cover layer 72 preferably comprise a coextruded material, having a first side of polypropylene and a second side of EVA, and having a thickness of from about 20 µm to about 30 µm, preferably about 25 µm (1 mil), wherein the polypropylene comprises about 50% and the EVA tie-layer comprises about 50% of the

total thickness of base layer 70 or cover layer 72. A particularly suitable material is available as P18-3161 from Clopay Plastics Products, Cincinnati, OH. The P18-3161 which is preferable for cover layer 72 has been subjected to a post process aperturing with hot needles to render it permeable to oxygen.

When coextruded materials of the type just described are used for base layer 70 and cover layer 72, the EVA sides are preferably oriented toward each other to facilitate thermal bonding of cover layer 72 to base layer 70.

Good overall drape characteristics and/or excellent conformity with user's upper back, neck, and/or shoulders, and/or increased structural support to the thermal pack 50, may also be achieved by selectively placing the heat cells 26 into positions fixed within or to the unified structure of the thermal pack 50 relative to each other which are sufficiently close so as to block some or all possible axes across the material of the continuous layer and/or layers 70 and/or 72, which otherwise would have passed uninterrupted between the heat cells 26, through the thermal pack 50, or select regions thereof, to minimize or eliminate undesirable, uninterrupted fold lines. That is, placement of the heat cells 26 into positions relative to each other which are sufficiently close so that the number of axes which pass uninterrupted, between the heat cells 26, is selectively controlled, such that the continuous base layer 70 and cover layer 72 of thermal pack 50, or select regions thereof, preferably folds along a multiplicity of short interconnected fold lines oriented in a number of different directions relative to each other. Folding along a multiplicity of interconnected fold lines results in thermal packs 50 which have good overall drape characteristics, readily conform with user's upper back, neck, and/or shoulders, and/or have increased structural support of the heat cell matrix.

Because heat cells 26 are not readily flexible, the spacing between heat cells 26 provides the preferred benefits and may be determined, when selectively placing heat cells 26 within or fixed to the unified structure of thermal packs 50, wherein at least one heat cell of four adjacent heat cells, whose centers form a quadrilateral pattern, blocks one or more axes that could otherwise form at least one fold line tangential to the edges of one or more pairings of the remaining three heat cells in the quadrilateral pattern. Preferably, the spacing between at least one heat cell of the four adjacent heat cells and each of the heat cells of the one or more pairings of the remaining heat cells in the quadrilateral pattern may be calculated using the equation:

$$s \leq (W_q/2) * 0.75$$

Where s = the closest distance between the heat cells; and
W_q = the measurement of the smallest diameter of the smallest diameter heat cell within the quadrilateral pattern.

Alternatively, the spacing between heat cells 26 may be determined wherein, at least one heat cell of three adjacent heat cells, whose centers form a triangular pattern, blocks one or more axes that could otherwise form at least one fold line tangential to the edges of the remaining pair of heat cells in the triangular pattern formed by the three heat cells. Most preferably, the spacing between the at least one heat cell of the three adjacent heat cells and each heat cell of the remaining pair of heat cells in the triangular pattern may be calculated using the equation:

$$s \leq (W_t/2) * 0.3$$

Where s = the closest distance between the heat cells; and
W_t = the measurement of the smallest diameter of the smallest diameter heat cell within the triangular pattern.

Different materials may be capable of satisfying the above specified requirements. Such materials may include, but are not limited to, those materials mentioned above.

A most preferred embodiment of the disposable thermal packs 50 of the present invention comprises at least one continuous layer of semirigid material having the thermophysical properties described above, and the heat cells 26 fixed within or to the unified structure of thermal pack 50 in positions relative to each other which are sufficiently close so as to block some or all possible axes across the material of the continuous layer(s) 70 and/or 72, which otherwise would have passed uninterrupted between heat cells 26, through thermal packs 50, or select regions thereof, to minimize or eliminate undesirable, uninterrupted fold lines, as described above.

Exothermic composition 74 may comprise any composition capable of providing heat. However, exothermic composition 74 preferably comprises a particulate mix of chemical compounds that undergo an oxidation reaction during use. Alternatively,exothermic composition 74 may also be formed into agglomerated granules, direct compacted into compaction articles such as granules, pellets, tablets, and/or slugs, and mixtures thereof. The mix of compounds typically comprises iron

powder, carbon, a metal salt(s), and water. Mixtures of this type, which react when exposed to oxygen, provide heat for several hours.

Suitable sources for iron powder include cast iron powder, reduced iron powder, electrolytic iron powder, scrap iron powder, pig iron, wrought iron, various steels, iron alloys, and the like and treated varieties of these iron powders. There is no particular limitation to their purity, kind, etc. so long as it can be used to produce heat-generation with electrically conducting water and air. Typically, the iron powder comprises from about 30% to about 80% by weight, preferably from about 50% to about 70% by weight, of the particulate exothermic composition.

Active carbon prepared from coconut shell, wood, charcoal, coal, bone coal, etc. are useful, but those prepared from other raw materials such as animal products, natural gas, fats, oils and resins are also useful in the particulate exothermic composition of the present invention. There is no limitation to the kinds of active carbon used, however, the preferred active carbon has superior water holding capabilities and the different carbons may be blended to reduce cost. Therefore, mixtures of the above carbons are useful in the present invention as well. Typically, activated carbon, non-activated carbon, and mixtures thereof, comprises from about 3% to about 25%, preferably from about 8% to about 20%, most preferably from about 9% to about 15% by weight, of the particulate exothermic composition.

The metal salts useful in the particulate exothermic composition include sulfates such as ferric sulfate, potassium sulfate, sodium sulfate, manganese sulfate, magnesium sulfate; and chlorides such as cupric chloride, potassium chloride, sodium chloride, calcium chloride, manganese chloride, magnesium chloride and cuprous chloride. Also, carbonate salts, acetate salts, nitrates, nitrites and other salts can be used. In general, several suitable alkali, alkaline earth, and transition metal salts exist which can also be used, alone or in combination, to sustain the corrosive reaction of iron. The preferred metal salts are sodium chloride, cupric chloride, and mixtures thereof. Typically, the metal salt(s) comprises from about 0.5% to about 10% by weight, preferably from about 1.0% to about 5% by weight, of the particulate exothermic composition.

The water used in the particulate exothermic composition may be from any appropriate source. There is no particular limitation to its purity, kind, etc. Typically, water comprises from about 1% to about 40% by weight, preferably from about 10% to about 30% by weight, of the particulate exothermic composition.

Additional water-holding materials may also be added as appropriate. Useful additional water-holding materials include vermiculite, porous silicates, wood powder, wood flour, cotton cloth having a large amount of fluffs, short fibers of cotton, paper scrap, vegetable matter, super absorbent water-swellable or water-soluble polymers and

resins, carboxymethylcellulose salts, and other porous materials having a large capillary function and hydrophilic property can be used. Typically, the additional water-holding materials comprise from about 0.1% to about 30% by weight, preferably from about 0.5% to about 20% by weight, most preferably from about 1% to about 10% by weight, of the particulate exothermic composition.

Other additional components include agglomeration aids such as gelatin, natural gums, cellulose derivatives, cellulose ethers and their derivatives, starch, modified starches, polyvinyl alcohols, polyvinylpyrrolidone, sodium alginates, polyols, glycols, corn syrup, sucrose syrup, sorbitol syrup and other polysaccharides and their derivatives, polyacrylamides, polyvinyloxoazolidone, and maltitol syrup; dry binders such as maltodextrin, sprayed lactose, co-crystallized sucrose and dextrin, modified dextrose, sorbitol, mannitol, microcrystalline cellulose, microfine cellulose, pre-gelatinized starch, dicalcium phosphate, and calcium carbonate; oxidation reaction enhancers such as elemental chromium, manganese, or copper, compounds comprising said elements, or mixtures thereof; hydrogen gas inhibitors such as inorganic or organic alkali compounds or alkali weak acid salts including sodium hydroxide, potassium hydroxide, sodium hydrogen carbonate, sodium carbonate, calcium hydroxide, calcium carbonate, and sodium propionate; fillers such as natural cellulosic fragments including wood dust, cotton linter, and cellulose, synthetic fibers in fragmentary form including polyester fibers, foamed synthetic resins such as foamed polystyrene and polyurethane, and inorganic compounds including silica powder, porous silica gel, sodium sulfate, barium sulfate, iron oxides, and alumina; and anti-caking agents such as tricalcium phosphate and sodium silicoaluminate. Such components also include thickeners such as cornstarch, potato starch, carboxymethylcellulose, and α-starch, and surfactants such as those included within the anionic, cationic, nonionic, zwitterionic, and amphoteric types. The preferred surfactant, if used however, is nonionic. Still other additional components which may be added to the particulate exothermic compositions of the present invention, as appropriate, include extending agents such as metasilicates, zirconium, and ceramics.

Preferably at least 50%, more preferably 70%, even more preferably 80% and most preferably 90% of all of the particles by weight of the particulate exothermic composition of the present invention have a mean particle size of less than 200 μm, preferably less than 150 μm.

The above-mentioned components of the composition are blended using conventional blending techniques. Suitable methods of blending these components are described in detail in U. S. Patent 4,649,895 to Yasuki et al., issued March 17, 1987 which is incorporated by reference herein in its entirety.

Alternatively to the above described particulate exothermic composition, the exothermic composition may be formed into agglomerated granules, direct compacted into compaction articles such as granules, pellets, tablets, and/or slugs, and mixtures thereof.

The exothermic composition of these agglomerated granules and/or compaction articles comprises iron powder, dry powdered carbonaceous material, an agglomeration aid, and a dry binder. Additionally, a metal salt, is added to the dry mix or subsequently as an aqueous/brine solution. Typically, the iron powder comprises from about 30% to about 80%, preferably from about 40% to about 70%, most preferably from about 50% to about 65% by weight; activated carbon, non-activated carbon, and mixtures thereof, comprises from about 3% to about 20%, preferably from about 5% to about 15%, most preferably from about 6% to about 12% by weight; the metal salt(s) comprises from about 0.5% to about 10%, preferably from about 1% to about 8%, most preferably from about 2% to about 6% by weight; the agglomeration aids comprise from about 0% to about 9%, preferably from about 0.5% to about 8%, more preferably from about 0.6% to about 6%, most preferably from about 0.7% to about 3% by weight; and the dry binder comprises from about 0% to about 35%, preferably from about 4% to about 30%, more preferably from about 7% to about 20%, most preferably from about 9% to about 15% by weight, of the agglomerated pre-compaction compositions of the present invention.

Heat cells comprising agglomerated granules are typically made using conventional blending techniques and agglomerated into granules.

Heat cells comprising compaction articles are preferably made by direct compaction of the dry ingredients into articles such as hard granules, pellets, tablets, and/or slugs. Suitable methods of making tablets and/or slugs are described in detail in Chapter 89, "Oral Solid Dosage Forms", <u>Remington's Pharmaceutical Sciences</u>, 18th Edition, (1990), pp. 1634-1656, Alfonso R. Gennaro, ed., incorporated herein by reference in its entirety. Any conventional tableting machine and compression pressures, up to the maximum provided by the machine can be used.

The tablets/slugs can have any geometric shape consistent with the shape of the heat cell, e.g., disk, triangle, square, cube, rectangle, cylinder, ellipsoid and the like, all or none of which may contain a hole through the middle or other reservoir. The preferred shape of the tablet/slug comprises a disk shaped geometry, having a concaved (whisper) configuration to the top and/or bottom of the tablet. The more preferred shape of the tablet/slug, however, comprises a disk shaped geometry, having a hole perpendicular to, and through the middle of the top and bottom of the tablet.

The size of the compacted disk is limited only by the size of the punches and die available and/or used in the tableting machine, as well as the size of the heat cell pocket. However, the disk typically has a diameter of from about 0.2 cm to about 10 cm, preferably from about 0.5 cm to about 8 cm, more preferably from about 1 cm to about 5 cm, and most preferably from about 1.5 cm to about 3 cm and a height of from about 0.08 cm to about 1 cm, preferably from about 0.15 cm to about 0.8 cm, more preferably from about 0.2 cm to about 0.6 cm, and most preferably from about 0.2 cm to about 0.5 cm. Alternatively, the compacted disk having a geometric shape other than a disk shape may have a width at its widest point of from about 0.15 cm to about 20 cm, preferably from about 0.3 cm to about 10 cm, more preferably from about 0.5 cm to about 5 cm, most preferably from about 1 cm to about 3 cm, a height at its highest point of from about 0.08 cm to about 1 cm, preferably from about 0.15 cm to about 0.8 cm, more preferably from about 0.2 cm to about 0.6 cm, and most preferably from about 0.2 cm to about 0.5 cm, and a length at its longest point of from about 1.5 cm to about 20 cm, preferably from about 1 cm to about 15 cm, more preferably from about 1 cm to about 10 cm, most preferably from about 3 cm to about 5 cm. The hole or reservoir should be large enough to substantially hold the prescribed amount of water and/or the water-carrying material. Typically, the hole has a diameter of from about 0.1 cm to about 1 cm, preferably from about 0.2 cm to about 0.8 cm, and more preferably from about 0.2 cm to about 0.5 cm.

The compaction articles of the present invention are compressed to the hardest possible mechanical strength to withstand the shocks of handling in their manufacture, packing, shipping, and dispensing. The compaction articles are typically compressed to a density of greater than about 1 g/cm^3, preferably from about 1 g/cm^3 to about 3 g/cm^3, more preferably from about 1.5 g/cm^3 to about 3 g/cm^3, and most preferably from about 2 g/cm^3 to about 3 g/cm^3.

Heat cells 26 comprising the above described components are typically formed by adding a fixed amount of a particulate exothermic composition or compaction article(s) 74 to a pocket or pockets made in a first continuous layer, i. e., continuous base layer 70. A second continuous layer, i. e., continuous cover layer 72, is placed over the first continuous layer, sandwiching the particulate exothermic composition or compaction article(s) between the two continuous layers which are then bonded together, preferably using a low heat, forming a unified, laminate structure. Preferably, each heat cell has a similar volume of heat generating material and has similar oxygen permeability means. However, the volume of the heat generating material, shape of the heat cell, and oxygen permeability may be different from heat cell to heat cell as long as

the resulting cell temperatures generated are within accepted therapeutic and safety ranges for their intended use.

The heat cells 26 of thermal pack 50 can have any geometric shape, e.g., disk, triangle, pyramid, cone, sphere, square, cube, rectangle, rectangular parallelepiped, cylinder, ellipsoid and the like. The preferred shape of the heat cells 26 comprises a disk shaped geometry having a cell diameter of from about 0.2 cm to about 10 cm, preferably from about 0.5 cm to about 8 cm, more preferably from about 1 cm to about 5 cm, and most preferably from about 1.5 cm to about 3 cm. The heat cells 26 have a height of from greater than about 0.2 cm to about 1 cm, preferably from greater than about 0.2 cm to about 0.9 cm, more preferably from greater than about 0.2 cm to about 0.8 cm, and most preferably from about 0.3 cm to about 0.7 cm. Alternatively, the heat cells having geometric shapes other than a disk shape, preferably an ellipsoid (i. e., oval), may have a width at its widest point of from about 0.15 cm to about 20 cm, preferably from about 0.3 cm to about 10 cm, more preferably from about 0.5 cm to about 5 cm, most preferably from about 1 cm to about 3 cm, a height at its highest point of from greater than about 0.2 cm to about 5 cm, preferably from greater than about 0.2 cm to about 1 cm, more preferably from greater than about 0.2 cm to about 0.8 cm, and most preferably from about 0.3 cm to about 0.7 and a length at its longest point of from about 0.5 cm to about 20 cm, preferably from about 1 cm to about 15 cm, more preferably from about 1 cm to about 10 cm, most preferably from about 3 cm to about 5 cm.

The ratio of fill volume to cell volume of the heat cells 26 is from about 0.7 to about 1.0, preferably from about 0.75 to about 1.0, more preferably from about 0.8 to about 1.0, even more preferably from about 0.85 to about 1.0, and most preferably from about 0.9 to about 1.0.

Oxygen permeability can be provided by selecting materials for the base layer 70 and/or cover layer 72 that have the specifically desired permeability properties. The desired permeability properties may be provided by microporous films or by films which have pores or holes formed therein. The formation of these holes/pores may be via extrusion cast/vacuum formation or by hot needle aperturing. The size of the apertures is preferably about 0.127 mm diameter, and there are preferably 25 to 40 apertures per heat cell 26. Another preferred method of making apertures is to pierce cell covering layer 72 with cold needles. Alternatively, apertures may be produced by a vacuum forming or a high pressure water jet forming process. Oxygen permeability may also be provided in the present invention by perforating at least one of the base layer 70 and cover layer 72 with aeration holes using, for example, an array of pins having tapered points and diameters of from about 0.2 mm to about 2 mm, preferably

from about 0.4 mm to about 0.9 mm. The array of pins is patterned such that the base layer 70 and/or cover layer 72 are perforated by from about 10 to about 30 pins per square centimeter. Alternatively, after the base layer 70 and cover layer 72 have been bonded together, enclosing the exothermic composition 74 in the pocket between them, one side of the heat cells 26 may be perforated with aeration holes using, for example, at least one pin, preferably an array of from about 20 to about 60 pins having tapered points and diameters of from about 0.2 mm to about 2 mm, preferably from about 0.4 mm to about 0.9 mm. The pins are pressed through one side of the base layer 70 and/or cover layer 72 to a depth of from about 2% to about 100%, preferably from about 20% to about 100%, and more preferably from about 50% to about 100% into the exothermic composition 74. This hole configuration provides an oxygen diffusion into the heat cell 26 during oxidation of the particulate exothermic composition 74 of from about 0.01 cc O_2/min./5 cm^2 to about 15.0 cc O_2/min./5 cm^2 (at 21°C, 1 ATM), preferably from about 0.9 cc O_2/min./5 cm^2 to about 3 cc O_2/min./5 cm^2 (at 21°C, 1 ATM).

The velocity, duration, and temperature of the thermogenic oxidation reaction of the exothermic composition 74 can be controlled as desired by changing the area of contact with air, more specifically, by changing the oxygen diffusion/permeability.

The disposable thermal neck wraps of the present invention may optionally incorporate a component, such as a separate substrate layer or incorporated into at least one of the continuous layers, comprising active aromatic compounds, non-active aromatic compounds, pharmaceutical actives or other therapeutic agents, and mixtures thereof, to be delivered through the skin. Such active aromatic compounds include, but are not limited to, menthol, camphor, and eucalyptus. Such non-active aromatic compounds include, but are not limited to, benzaldehyde, citral, decanal, and aldehyde. Such pharmaceutical actives/therapeutic agents include, but are not limited to antibiotics, vitamins, antiviral agents, analgesics, anti-inflammatory agents, antipruritics, antipyretics, anesthetic agents, antifungals, antimicrobials, and mixtures thereof. The disposable thermal neck wraps may also comprise a separate substrate layer, or incorporated into at least one of the continuous layers, a self-adhesive component and/or a sweat-absorbing component.

The finished disposable thermal neck wraps are typically packaged in a secondary package. An air-impermeable package may be used to prevent an oxidation reaction from occurring until desired as described in U.S. Patent 4,649,895, incorporated herein by reference in its entirety. Alternatively, other means may also be used to prevent an oxidation reaction from occurring before desired, such as air impermeable removable adhesive strips placed over the aeration holes in the heat cells such that,

when the strips are removed, air is allowed to enter the heat cells, thus activating the oxidation reaction of the iron powder.

The present invention further comprises a method for treating acute, recurrent, and/or chronic upper back, neck, and/or shoulder pain, including muscular, skeletal, and/or referred upper back, neck, and/or shoulder pain, of a person suffering such pain by topically applying heat to the specific areas of the upper back, neck, and/or shoulders of a person suffering such pain. The method comprises maintaining a skin temperature to the upper back, neck, and/or shoulder of a person suffering such pain of from about 32°C to about 50°C, preferably from about 32°C to about 45°C, more preferably from about 32°C to about 42°C, most preferably from about 32°C to about 39°C, still most preferably from about 32°C to about 37°C, preferably by applying the above described neck wraps to the upper back, neck, and/or shoulder of a person suffering such pain, for from about twenty seconds to about twenty-four hours, preferably from about twenty minutes to about twenty hours, more preferably from about four hours to about sixteen hours, most preferably from about eight hours to about twelve hours, wherein the maximum skin temperature and the length of time of maintaining the skin temperature at the maximum skin temperature may be appropriately selected by a person needing such treatment, such that the desired therapeutic benefits are achieved, without any adverse events, such as skin burns which may be incurred by using a high temperature for a long period of time.

Preferably the method comprises maintaining a sustained skin temperature to the upper back, neck, and/or shoulders of a person having acute, recurrent, and/or chronic upper back, neck, and/or shoulder pain, including muscular, skeletal, and/or referred upper back, neck, and/or shoulder pain, of from about 32°C to about 43°C, preferably from about 32°C to about 42°C, more preferably from about 32°C to about 41°C, most preferably from about 32°C to about 39°C, still most preferably from about 32°C to about 37°C, for a time period of greater than about 1 hour, preferably greater than about 4 hours, more preferably greater than about 8 hours, even more preferably greater than about 16 hours, most preferably about 24 hours, to substantially relieve acute, recurrent, and/or chronic upper back, neck, and/or shoulder pain, including skeletal, muscular, and/or referred upper back, neck, and/or shoulder pain, of a person having such pain and to substantially prolong relief, for at least about 2 hours, preferably for at least about 8 hours, more preferably for at least about 16 hours, most preferably for at least about one day, still most preferably for at least about three days, from such pain, even after the heat source is removed from the upper back, neck, and/or shoulders of the user.

While particular embodiments of the present invention have been illustrated and described, it will be obvious to those skilled in the art that various changes and

modifications may be made without departing from the spirit and scope of the invention, and it is intended to cover in the appended claims all such modifications that are within the scope of the invention.

WHAT IS CLAIMED IS:

1. A disposable thermal neck wrap comprising at least one substantially U-shaped piece of flexible material, said piece of flexible material having a first arm portion, a second arm portion, and a central body portion therebetween, such that when said neck wrap is placed on a user, said central body portion is centered at said user's upper back and lower neck and said first and second arm portions lay across said user's shoulders toward said user's chest, and one or more thermal packs, wherein said thermal packs having a unified structure comprising at least one continuous layer of a semirigid material having a tensile strength of 0.7 g/mm^2 or greater, preferably 0.85 g/mm^2 or greater, more preferably 1 g/mm^2 or greater, and at least two-dimensional drape at a temperature of 25°C, and wherein said material has a tensile strength, at a temperature of 35°C or greater, substantially less than said tensile strength of said material at 25°C, and having a plurality of individual heat cells spaced apart and fixed within or to said unified structure of said thermal pack, wherein said disposable thermal neck wrap further preferably comprises a positioning means, preferably one or more adhesive patches, attached to distal ends of at least one of said first and second arm portions, and wherein more preferably one or more of said heat cells of said thermal packs are located within each of said arms.

2. A disposable thermal neck wrap according to Claim 1 wherein said at least one continuous layer comprises a material consisting of polyethylene, polypropylene, nylon, polyester, polyvinyl chloride, polyvinylidene chloride, polyurethane, polystyrene, saponified ethylene-vinyl acetate copolymer, ethylene-vinyl acetate copolymer, natural rubber, reclaimed rubber, synthetic rubber, or mixtures thereof, preferably an extruded material consisting of polyethylene, polypropylene, nylon, polyester, polyvinyl chloride, polyvinylidene chloride, polyurethane, polystyrene, saponified ethylene-vinyl acetate copolymer, or ethylene-vinyl acetate copolymer, more preferably a coextruded material having a first side consisting of polyethylene, polypropylene, nylon, polyester, polyvinyl chloride, polyvinylidene chloride,

polyurethane, and polystyrene, and a second side consisting of saponified ethylene-vinyl acetate copolymer and ethylene-vinyl acetate copolymer, most preferably a coextruded material having a first side of polypropylene and a second side of ethylene-vinyl acetate copolymer, wherein said polypropylene preferably comprises from 10% to 90%, more preferably from 40% to 60%, of the total thickness of said material.

3. A disposable thermal neck wrap comprising at least one substantially U-shaped piece of flexible material, said piece of flexible material having a first arm portion, a second arm portion, and a central body portion therebetween, such that when said neck wrap is placed on a user, said central body portion is centered at said user's upper back and lower neck and said first and second arm portions lay across said user's shoulders toward said user's chest, and at least one thermal pack having a unified structure comprising at least one continuous layer of material and a plurality of individual heat cells placed into positions fixed within or to said unified structure of said thermal pack which are sufficiently close and relative to each other, so as to block some or all possible axes across said at least one continuous layer, which otherwise would have passed uninterrupted between said heat cells, through said thermal pack, or select regions thereof, preferably wherein at least one of said heat cells of four adjacent said heat cells, whose centers form a quadrilateral pattern, blocks one or more of said axes that could otherwise form at least one fold line tangential to the edges of one or more pairings of the remaining said heat cells in the quadrilateral pattern, more preferably wherein the spacing between said at least one of said heat cells and each of said heat cells of said one or more pairings of said remaining heat cells in said quadrilateral pattern is the same or less than the spacing obtained by dividing the measurement of the smallest diameter of the smallest diameter heat cell of said heat cells within said quadrilateral pattern by 2 and multiplying the result by 0.75, and further preferably comprising a positioning means, preferably one or more adhesive patches, attached to distal ends of at least one of said first and second arm portions, and wherein more preferably one or more of said heat cells of said thermal packs are located within each of said arms.

4. A disposable thermal neck wrap according to Claim 3 wherein at least one of said heat cells of three adjacent said heat cells, whose centers form a triangular pattern, blocks one or more of said axes that could otherwise form at least one fold line tangential to the edges of the remaining pair of said heat cells in the triangular pattern formed by said three heat cells, preferably wherein the spacing between said at least one of said heat cells and each of said heat cells of said remaining pair of said heat cells in said triangular pattern is the same or less than the spacing obtained by dividing the measurement of the smallest diameter of the smallest diameter heat cell of said heat cells within said triangular pattern by 2 and multiplying the result by 0.3.

5. A disposable thermal neck wrap according to Claim 3 or 4 wherein said at least one continuous layer comprises a semirigid material having a tensile strength of 0.7 g/mm^2, or greater, and at least two-dimensional drape at a temperature of 25°C, and wherein said material has a tensile strength, at a temperature of 35°C or greater, substantially less than said tensile strength of said material at 25°C, preferably said at least one continuous layer comprises a material consisting of polyethylene, polypropylene, nylon, polyester, polyvinyl chloride, polyvinylidene chloride, polyurethane, polystyrene, saponified ethylene-vinyl acetate copolymer, ethylene-vinyl acetate copolymer, natural rubber, reclaimed rubber, synthetic rubber, or mixtures thereof, more preferably said at least one continuous layer comprises a coextruded material having a first side consisting of polyethylene, polypropylene, nylon, polyester, polyvinyl chloride, polyvinylidene chloride, polyurethane, or polystyrene, and a second side consisting of saponified ethylene-vinyl acetate copolymer or ethylene-vinyl acetate copolymer, most preferably said at least one continuous layer comprises a coextruded material having a first side of polypropylene and a second side of ethylene-vinyl acetate copolymer, wherein said polypropylene preferably comprises from 10% to 90%, more preferably from 40% to 60%, of the total thickness of said material.

6. A disposable thermal neck wrap according to any preceding claim wherein said heat cells comprise a shape consisting of a disk, triangle, pyramid, cone, sphere, square, cube, rectangle, rectangular parallelepiped, cylinder, or ellipsoid, said disk having a diameter of from 1 cm to 5 cm and a height of from greater than 0.2 cm to 1 cm, and said triangle, pyramid, cone, sphere, square, cube, rectangle, rectangular parallelepiped, cylinder, or ellipsoid having a width at its widest point of from 0.5 cm to 5 cm and a height at its highest point of from greater than 0.2 cm to 1 cm and a length at its longest point of from 1.5 cm to 10 cm, and wherein said heat cells, when filled with an exothermic composition, have a fill volume to cell volume ratio of from 0.7 to 1.0.

7. A disposable thermal neck wrap according to any preceding claim wherein said exothermic composition comprises from 30% to 80% by weight, iron powder, from 3% to 25% by weight, carbonaceous material consisting of activated carbon, non-activated carbon, or mixtures thereof, from 0.5% to 10% by weight, metal salt, from 1% to 40% by weight, water, and preferably from 0.1% to 30% by weight, of additional water-holding material.

8. A disposable thermal neck wrap according to any preceding claim wherein said exothermic composition comprises from 30% to 80% by weight, of iron powder, from 3% to 20% by weight, of carbonaceous material consisting of activated carbon, non-activated carbon, or mixtures thereof, from 0% to 9% by weight, of an agglomeration aid consisting of corn syrup, maltitol syrup, crystallizing sorbitol syrup, amorphous sorbitol syrup, or mixtures thereof, from 0% to 35 % by weight, of a dry binder consisting of microcrystalline cellulose, maltodextrin, sprayed lactose, co-crystallized sucrose and dextrin, modified dextrose, mannitol, microfine cellulose, pre-gelatinized starch, dicalcium phosphate, calcium carbonate, or mixtures thereof, preferably said dry binder comprises from 4% to 30% by weight, of microcrystalline cellulose, more preferably from 0.5% to 10% by weight, of additional water-holding materials consisting of acrylic acid salt starch co-polymer, isobutylene maleic anhydride co-polymer, vermiculite, carboxymethylcellulose, or

mixtures thereof, wherein from 0.5% to 10% by weight, of a metal salt consisting of alkali metal salts, alkaline earth metal salts, transitional metal salts, or mixtures thereof is added to said composition as part of the dry mix or subsequently in an aqueous solution as brine, and wherein further said exothermic composition comprises a physical form consisting of dry agglomerated granules, direct compaction articles, or mixtures thereof, wherein said direct compaction articles are consisting of granules, pellets, tablets, slugs, or mixtures thereof, and wherein said tablets and slugs comprise a geometric shape consisting of disk, triangle, square, cube, rectangle, cylinder, or ellipsoid, said disk having a diameter of from 1 cm to 5 cm and a height of from 0.08 cm to 1 cm and said triangle, square, cube, rectangle, cylinder, or ellipsoid having a width at its widest point of from 0.5 cm to 5 cm and a height at its highest point of from 0.08 cm to 1 cm and a length at its longest point of from 1 cm to 10 cm, preferably wherein said direct compaction articles comprise a density of greater than 1 g/cm^3.

9. A disposable thermal neck wrap according to any preceding claim further comprising additional components consisting of active aromatic compounds, non-active aromatic compounds, pharmaceutical actives, or mixtures thereof.

10. A method of treating upper back, neck, and shoulder pain, consisting of acute muscular, acute skeletal, acute referred, recurrent muscular, recurrent skeletal, recurrent referred, chronic muscular, chronic skeletal, or chronic referred upper back, neck, and shoulder pain, by applying a disposable thermal neck wrap of any preceding claim to the upper back, neck, and shoulders of a person needing such treatment, to maintain a skin temperature to the back of from 32°C to 50°C, preferably from 32°C to 39°C, for a time period of from twenty seconds to twenty-four hours, wherein said skin temperature and said period of time of maintaining said skin temperature is appropriately selected by said person needing such treatment, to substantially relieve said pain without adverse events, preferably wherein said skin temperature is maintained at a temperature of from 32°C to 43°C for a time period of greater than 1 hour, preferably from 32°C to 41°C for a time

period of greater than 4 hours, wherein said relief of said pain is substantially prolonged for at least 2 hours, preferably for at least 1 day, after removal of said heat from the upper back, neck, and shoulders of said person needing such treatment.

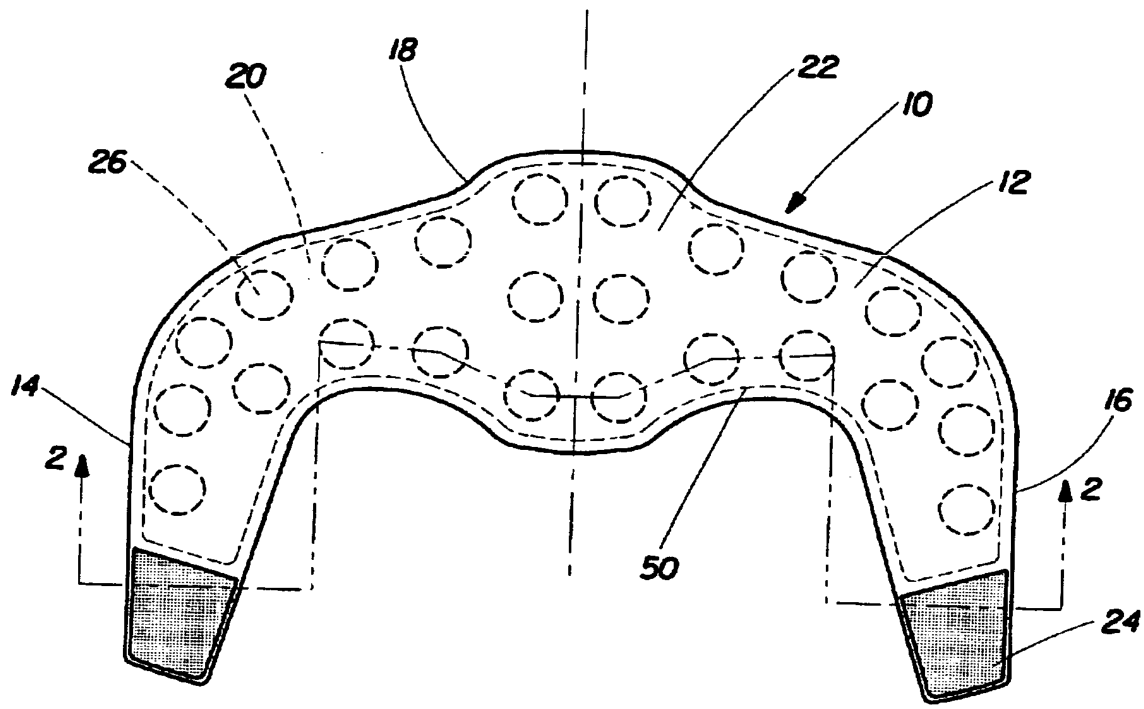

Fig. 1

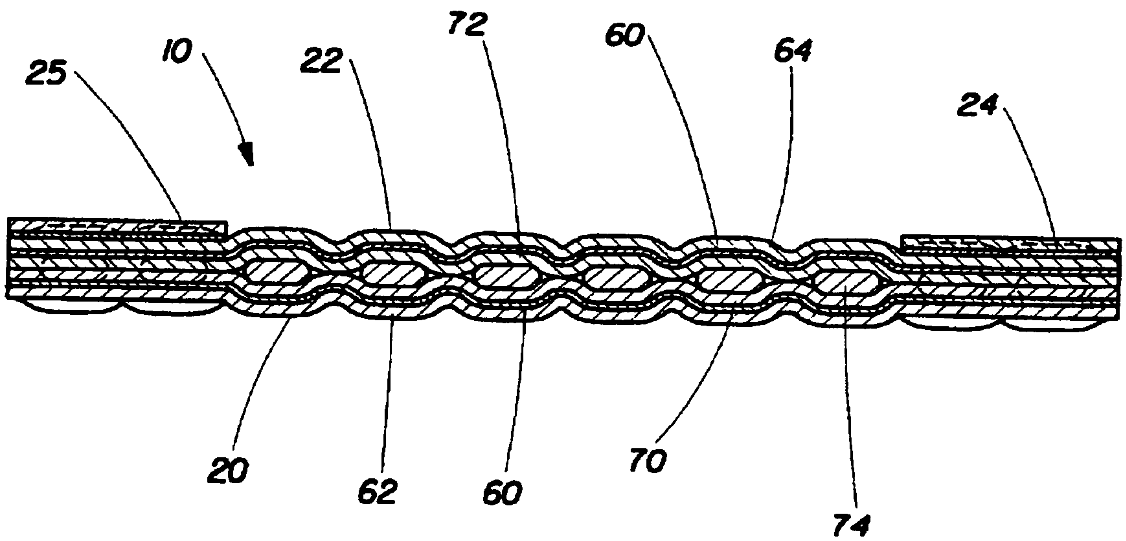

Fig. 2

DOCKET NO: WSO-41953
SERIAL NO: 10/629,926
APPLICANT: Gluderer

LERNER AND GREENBERG P.A.
P.O. BOX 2480
HOLLYWOOD, FLORIDA 33022
TEL. (954) 925-1100